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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,983	05/01/2008	Edward M. Boyle JR.	075.P001PCTUS	6421

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EXAMINER	
AVIGAN, ADAM JOSEPH	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
11/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,983	BOYLE ET AL.	
	Examiner	Art Unit	
	ADAM AVIGAN	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☒ An election was made by the applicant in response to a restriction requirement set forth during the interview on *10/27/2011*; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-34* is/are pending in the application.

5a) Of the above claim(s) *12-17 and 19-34* is/are withdrawn from consideration.

6)☒ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-11 and 18* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *10 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the application filed 5/1/2008. Claims 1-34 are restricted and claims 1-11 and 18 are provisionally elected by the applicant. Claims 1-11 and 18 are rejected by the examiner.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

5. Group I, claim(s) 1-18, drawn to a treatment catheter.

6. Group II, claim(s) 19-34, drawn to a method of treating a first tissue layer while protecting a second tissue layer from treatment.

7. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical features shared by group I and group II are "a shaft having a shaft distal end and a shaft proximal end; a treatment head disposed about the shaft distal end, the treatment head adapted to present a low profile in a closed state and a broad profile in a deployed state, the treatment head adapted to percutaneously treat one of first and second tissue layers and protect the other of the first and second tissue layers from the treatment." These

elements cannot be the special technical features since they are disclosed in the prior art by Parins et al. (US 5078717) (hereinafter Parins). Parins teaches a shaft (fig. 8, inner tube 62) having a shaft distal end and a shaft proximal end (fig. 8, inherent); a treatment head disposed about the shaft distal end (fig. 9, carrier member 68), the treatment head adapted to present a low profile in a closed state and a broad profile in a deployed state (fig. 8, displays the closed profile, fig. 9, displays the open profile), the treatment head adapted to percutaneously treat one of first and second tissue layers and protect the other of the first and second tissue layers from the treatment (fig. 9, carrier member 68 inherently treats tissues disposed adjacent to its proximal surface and shields tissues disposed adjacent to its distal surface).

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species I: claims 2-11

Species II: claims 12-16

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: claims 1 and 18.

REQUIREMENT FOR UNITY OF INVENTION

11. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

12. The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

13. As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

14. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

15. During a telephone conversation with Robert Beck on 10/27/11 a provisional election was made without traverse to prosecute the invention of group I, species I, claims 1-11 and 18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-17 and 19-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Parins et al. (US 5078717) (hereinafter Parins).

19. Regarding claims 1, Parins teaches a shaft (fig. 8, inner tube 62) having a shaft distal end and a shaft proximal end (fig. 8, inherent); a treatment head disposed about the shaft distal end (fig. 9, carrier member 68), the treatment head adapted to present a low profile in a closed state and a broad profile in a deployed state (fig. 8 displays the closed profile, fig. 9 displays the open profile), the treatment head adapted to percutaneously treat one of first and second tissue layers and protect the other of the first and second tissue layers from the treatment (fig. 9, carrier member 68 inherently treats tissues disposed adjacent to its proximal surface and shields tissues disposed adjacent to its distal surface).

20. Regarding claim 18, Parins further teaches the shaft further comprising a first lumen configured and dimensioned to receive a guide wire for directing the catheter (fig. 1, guide wire 30 is received by a lumen).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims 2-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parins in view of Friedman (US 20030093072).

24. Regarding claims 2 and 11, Parins teaches a canopy (fig. 9, carrier member 68 and surface 80) having a protection side facing a direction distal from the shaft (fig. 9, surface 80 shields tissues distal to the catheter from electrodes 72 and 74) and a treatment side facing a direction proximate the shaft (fig. 9, electrodes 72 and 74 are located on the proximal surface of 80). Parins fails to teach the canopy supported by a frame assembly comprising a runner, a plurality

of main ribs, a supporting rib coupled to each main rib, and an upper joint, the runner coupled to the shaft and moveable in an axial direction thereon, each main rib having a main rib outer end and a main rib inner end pivotally coupled to the shaft distal end at the upper joint, each supporting rib having a supporting rib inner end pivotally coupled to the runner and a supporting rib outer end pivotally coupled to the main rib, wherein the movement of the runner along the shaft from distal the upper joint to proximate the upper joint positions the frame assembly between a closed and deployed position, and therefore closes and deploys the canopy.

25. Friedman teaches a tissue ablation catheter having a having a retractable deployable umbrella body (pg. 1, par. 5) comprising a canopy (fig. 5, membranous material 35) supported by a frame assembly comprising a runner (fig. 3a, slideable deployment/retractor collar 24), a plurality of main ribs (fig. 3a, splines 22), a supporting rib coupled to each main rib (fig. 3a, connector rods 34), and an upper joint (fig. 3a, central hub 28), the runner coupled to the shaft and moveable in an axial direction thereon (fig. 3a, slideable deployment/retractor collar 24), each main rib having a main rib outer end and a main rib inner end (fig. 3a, splines 22, inherent) pivotally coupled to the shaft distal end at the upper joint (fig. 3a, splines 22 are pivotally coupled to hub 28), each supporting rib having a supporting rib inner end pivotally coupled to the runner and a supporting rib outer end pivotally coupled to the main rib (fig. 3a, one end of connector rods 34 is coupled to collar 24, the other end is coupled to splines 22), wherein the movement of the runner along the shaft from distal the upper joint to proximate

the upper joint positions the frame assembly between a closed and deployed position, and therefore closes and deploys the canopy (pg. 3 par. 32, fig. 3a).

26. Because both Parins and Friedman teach methods for deploying a deployable/retractable canopy at the distal end of a treatment catheter, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to substitute one method for the other in order to achieve the predictable result of deploying a deployable/retractable canopy at the distal end of a treatment catheter. KSR Int'l Co. V. Teleflex Inc., 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007)

27. Regarding claim 3, Parins, as modified, further teaches wherein the treatment side comprises treatment elements (see Parins, fig. 9, electrodes 72 and 74 are disposed on the proximal side of surface 80).

28. Regarding claim 4, Parins, as modified, further teaches wherein the treatment elements radiate from a central portion of the treatment side (see Parins, fig. 10, electrodes 72 and 74 are located in a radial direction from the center of carrier member 68)

29. Regarding claim 6, Parins, as modified, further teaches wherein the treatment elements are present in discrete locations on the treatment side (see Parins, fig. 10, electrodes 72 and 74 are located discretely from each other).

30. Regarding claims 7 and 10, Parins, as modified, further teaches wherein the heating elements are resistive heating elements that provide a predetermined amount of energy and wherein the treatment elements comprise radio-frequency

emitting elements that provide a predetermined amount of RF. (see Parins, fig. 9, electrodes 72 and 74, col. 2 lines 25-30).

31. Regarding claim 8 and 9, Parins, as modified, further teaches wherein the treatment elements are fiber optic elements that are adapted to provide a predetermined amount of laser energy (see Friedman, pg. 2, par. 16) and wherein the treatment elements are adapted to discharge fluid (see Friedman, pgs. 3-4, par. 35).

32. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parins in view of Friedman as applied to claims 2-4 and 6-11 above, and further in view of Edwards (US 6056744).

33. Regarding claim 5, Parins, as modified, teaches treatment elements disposed on the treatment side of a canopy but fails to teach wherein the treatment elements radiate in a spiral pattern from a central portion of the treatment side.

34. Edwards teaches several different distribution patterns of treatment elements on the surfaces of expansion devices, including a spiral distribution (fig. 18c, electrodes 88 are arranged spirally on the surface of expansion device 20). Because both Parins and Edwards teach distribution patterns of treatment elements disposed on the surfaces of expansion devices, it would have been obvious to one of ordinary skill in the art at time that the invention was made to substitute one distribution pattern for the other in order to achieve the predictable result of an electrode distribution pattern on the surface of an expansion device.

KSR Int'l Co. V. Teleflex Inc., 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM AVIGAN whose telephone number is (571)270-3953. The examiner can normally be reached on Monday-Thursday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571 272 4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ADAM AVIGAN/
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art

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